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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/011,910 02/17/98 ABRIGNANI

S 0336.001

EXAMINER

HM12/0206

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BRIMBACK, B
ART UNIT

PAPER NUMBER

18

1642
DATE MAILED:

02/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/011,910

Applicant(s)

Abrignani

Examiner
Brenda Brumback

Group Art Unit
1642



☒ Responsive to communication(s) filed on Jan 8, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2-4, 7-10, 13, 14, and 17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 2-4, 7-10, 13, 14, and 17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. This action is responsive to the amendment filed 01/08/2000. Claims 6, 11, and 12 were canceled. Claims 2-4, 7-10, 13, 14, and 17 are pending and examined on the merits.
2. The finality of the Office action mailed 03/03/2000 is hereby withdrawn in light of the new grounds of rejection which follow.

Specification

3. The objection to the specification as not containing an abstract is withdrawn subsequent to applicant's submission thereof.

Claim Rejections - 35 USC § 112

4. The rejection of claims 2-4, 7-10, 13, 14, and 17 under 35 U.S.C. 112, second paragraph, for recitation of a functionally equivalent variant or fragment thereof is withdrawn due to applicant's amendment and arguments, which were persuasive. A functionally equivalent variant or fragment of the claimed protein is understood to mean a variant or fragment which binds to the E2 protein of HCV.

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5. The rejection of claims 2-4, 7-10, 13, 14, and 17 under 35 U.S.C. 112, second paragraph, for recitation of a functionally unglycosolated protein and the rejection of claims 8 and 9 for recitation of at least one step of hydrophobic interaction chromatography and at least one step of acetone precipitation are withdrawn due to applicant's amendment thereof and arguments, which were persuasive. The rejection of claim 6 for "hyperexpression" is moot since claim 6 has been canceled.

6. The rejection of claims 2-4, 7-10, 13, 14, and 17 under 35 U.S.C 112, first paragraph for "functionally equivalent variant or fragment thereof" is withdrawn. The rejection of claims 11 and 12 under 35 U.S.C. 112, first paragraph, is now moot, as these claims have been canceled.

7. The rejection of claims 2-4, 7-10, and 13 under 35 U.S.C. 112, second paragraph, as incomplete for omitting an essential step is withdrawn pursuant to applicant's amendment thereof. Claim 1 has been canceled.

Claim Rejections - 35 USC § 102

8. The rejection of claim 17 under 35 U.S.C. 102(b) or 103(a) as anticipated by or in the alternative as obvious over Mehta et al. is withdrawn due to applicant's amendment thereof and arguments, which were persuasive..

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NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

9. Claims 13 and 14, which are drawn to a composition for use as a pharmaceutical and to a method of making a pharmaceutical composition, are rejected under 35 U.S.C., first paragraph, for the reasons of record for original claims 11 and 12 (see Paper # 6, pages 8-10), as these claims encompass making and using the claimed composition for *in vivo* therapy.

Applicant's arguments regarding therapeutic administration *in vivo* have been previously addressed in Papers # 12 (see page 4) and # 10 (the paragraph bridging pages 5 and 6).

10. Claims 2-4, 7-10, 13, 14, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "... protein, or a functionally equivalent variant or fragment thereof, is a transmembrane protein". It is unclear how a variants and fragments of a transmembrane protein could be themselves be considered to be transmembrane proteins. It is suggested that the phrase "or a functionally equivalent variant or fragment thereof" be eliminated from this claim.

Claims 4, 10, 13, 14 and 17 recite a protein "capable of specifically binding" to E2 of hepatitis C virus. The phrase "capable of" renders the claims indefinite because it connotes the necessity for existence of some undefined condition or parameter before binding can actually occur. Furthermore, for clarification, the claims should be amended to recite "the E2 protein"

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rather than simply "E2". It is suggested that the claims be amended something like "... a protein having a molecular weight of about 24 kd which binds specifically to the E2 protein of hepatitis C virus".

Claim 10 (step v) recites "resuspending". The term "resuspending" denotes suspending the precipitate back into the original rough cellular preparation. It is suggested that the claim be amended something like "suspending the precipitate from step iv in buffer".

The syntax of claims 13, 14, and 17 renders the claims indefinite, as it is unclear whether the protein, the variant or fragment thereof, or both bind the E2 protein of hepatitis C virus. It is suggested that the claims be amended something like "... a protein having a molecular weight of about 24 kd which specifically binds the E2 protein of hepatitis C virus, or a functionally equivalent variant or fragment thereof ...".

Conclusion

11. Due to the new grounds of rejection, this action is made nonfinal. Any inconvenience is regretted.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and

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should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

February 6, 2001

Brenda Brumback
Brenda Brumback,
Patent Examiner